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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/701,989

01/29/2001

Alexandros Makriannis

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1360

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7590

03/26/2002

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EXAMINER

OSTRUP, CLINTON T

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/701,989

Applicant(s)

MAKRIYANNIS ET AL.

Examiner

Clinton Ostrup

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 January 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-14 are pending in this application.

Priority

Priority to US Provisional Application Number 60/088,568 filed June 9, 1998 and PCT/US99/12900, filed June 9, 1999 has been acknowledged.

Claim Rejections - 35 USC § 112

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

w/d
Claims 1 and 8 are confusing because of the phraseology "the middle portion of". The claims are confusing because it is unclear and difficult to determine what constitutes the middle portion. The examiner respectfully suggests deleting the phrase "the middle portion of" to clarify the claims, as this phrase is superfluous and adds no patentable limitation to the claims.

Any remaining claims are rejected as depending from indefinite base claims.

Double Patenting

maintain
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-14 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 and 12-19 of copending Application No. 09/328,742. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both drawn to compounds and methods of inhibiting the transport of anandamide in an individual or animal by administration of said compounds to said individual or animal. The compounds and methods of administering said compounds overlap one another in the conflicting claims and/or are obvious variants of one another.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

u/d
Claims 8, 10, 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Mechoulam et al., **5,618,955**.

The reference teaches the use of fatty acid amides and their derivatives for the treatment of inflammation, migranes, spasticity activity, glaucoma, and multiple sclerosis. The compositions as taught and claimed by the reference meet the compounds as claimed instantly in claims 8, 10, and 12-13. See: col. 7-8, abstract, and figures 4A and 9A-9F.

Claims 1, 3, 5, 6, 8, 10, 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Nelson 4,497,827.

Nelson teaches amide derivatives of unsaturated fatty acids which are selective inhibitors of the enzymes lipoxxygenase and cyclooxygenase involved in the production of pain, inflammation, bronchoconstriction and allergic reactions. The reference teaches arachidonamide and pharmaceutical compositions thereof as beneficial in the treatment of a number of inflammatory and/or painful conditions and allergic reactions by selective inhibitory activity on the enzymes involved in the metabolic synthetic pathways of prostaglandins, leucotrienes or thromboxanes. Nelson teaches amide derivatives of unsaturated fatty acids which are selective inhibitors of the enzymes lipoxxygenase and cyclooxygenase involved in the production of pain, inflammation, bronchoconstriction and allergic reactions. The secondary reference teaches that these compounds are beneficial in the treatment of a number of inflammatory and/or painful

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conditions and allergic reactions. See: col. 1, lines 5-29; col. 3, line 24 – col. 4, line 46; col. 11, line 65 – col. 12, line 33.

The secondary reference teaches that Arachidonic acid is the biological precursor of such pro-inflammatory agents as prostaglandins and leucotrienes, or the platelet aggregation inducers thromboxanes and that the compositions of the invention will inhibit the activity of the enzymes involved in these metabolic synthetic pathways.

See: col. 1, lines 17-30 and abstract.

Therefore, the compositions comprising arachidonamide as taught by Nelson would inherently inhibit the transport of anandamide as claimed instantly in claims 1,3,5, and 6.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on M-F (8:30am-5:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Clinton Ostrup
Examiner
Art Unit 1614

March 19, 2002

FREDERICK MASS
PRIMARY EXAMINER
GROUP 1600

Fredrick